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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER
ANDERSON, MICHAEL J

ART UNIT	PAPER NUMBER
3767	

MAIL DATE	DELIVERY MODE
10/23/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/811,500

Applicant(s)

MCCLURE ET AL.

Examiner

Michael J. Anderson

Art Unit

3767

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 March 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 9/16/2004, and 6/16/2004.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

Information Disclosure Statement

The references cited have been considered, and will be listed on any patent resulting from this application since they were provided on a separate list in the Information Disclosure Statement (IDS) Form PTO/SB/08 in compliance with 37 CFR 1.98(a)(1).

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the biasing element ("spring") must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet"

pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 6-7 and 27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The biasing element ("spring") is not shown in the figures.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 5, 8-16 and 18-26 are rejected under 35 U.S.C. 102(b) as being anticipated by Harris (US Patent No. 6,540,724 B1) (Hereafter, Harris).

With regards to claim 1, Harris discloses (figures 1-8) a removable protective cover for an exposed portion of a medical device extending along a

longitudinal axis from a body, the cover comprising: a housing defining an opening along a single edge to receive the exposed portion, the edge intersecting the axis, and the edge being sealable to enclose the exposed portion within the housing (figure 3).

With regards to claim 2, Harris discloses (figures 1-8) the cover claimed in claim 1, and further discloses the housing comprising a pair of opposing walls defining a sealable pocket (paragraph [0005]).

With regards to claim 3, Harris discloses (figures 1-8) the cover claimed in claim 2, and further discloses the pocket being made of one or more flexible materials (paragraph [0005]).

With regards to claim 5, Harris discloses (figures 1-8) the cover claimed in claim 1, and further discloses the edge being operable between a closed position and an open position by operation of a single hand.

With regards to claim 8, Harris discloses (figures 1-8) the cover claimed in claim 1, and further discloses comprising adhesive along the first edge to releasably seal the opening.

With regards to claim 9, Harris discloses (figures 1-8) the cover claimed in claim 1, and further discloses the edge being defined along a single plane in sealable contact with the body.

With regards to claim 10, Harris discloses (figures 1-8) the cover claimed in claim 9, and further discloses, the plane comprising a band of adhesive encircling the opening for releasably securing the cover directly to the body,

Art Unit: 3767

about an entry point through which the medical device extends into the body (column 4, lines 3-19).

With regards to claim 11, Harris discloses (figures 1-8) the cover claimed in claim 9, and further discloses the plane comprising a band for releasably securing the cover directly to the body (column 4, lines 8-19).

With regards to claim 12, Harris discloses (figures 1-8) the cover claimed in claim 11, and further discloses the band comprising an adhesive to secure the cover to the body, thereby forming a barrier about the entry point (column 4, lines 3-19).

With regards to claim 13, Harris discloses (figures 1-8) the cover claimed in claim 1, and further discloses it further comprising a display for treatment information (column 4, lines 3-19)..

With regards to claim 14, Harris discloses (figures 1-8) kit for covering an exposed portion of a medical device extending outwardly from a body, the kit comprising: a first housing defining an opening along an edge, the edge being sealable to enclose the exposed portion within the first housing; and a second housing receiving the first housing, the second housing being releasably securable to the body, about an entry point through which the medical device extends into the body.

With regards to claim 15, Harris discloses (figures 1-8) the cover claimed in claim 14, and further discloses the first housing defining a pocket comprising a first set of two opposing walls.

Art Unit: 3767

With regards to claim 16, Harris discloses (figures 1-8) the cover claimed in claim 15, and further discloses the first set of opposing walls being made of one or more flexible materials.

With regards to claim 18, Harris discloses (figures 1-8) the cover claimed in claim 14, and further discloses the second housing comprising a band for releasably securing the second housing directly to the body (column 4, lines 8-19).

With regards to claim 19, Harris discloses (figures 1-8) the cover claimed in claim 18, and further discloses the band comprising an adhesive to secure the second housing directly to the body, about an entry point through which the medical device extends from the body (column 4, lines 8-19).

With regards to claim 20, Harris discloses (figures 1-8) the cover claimed in claim 19, and further discloses the band forming an impermeable barrier about the entry point.

With regards to claim 21, Harris discloses (figures 1-8) the cover claimed in claim 20, and further discloses, the second housing comprising a second set of opposing walls made from one or more flexible materials to form an impermeable barrier.

With regards to claim 22, Harris discloses (figures 1-8) the cover claimed in claim 14, and further discloses the first housing being visible through the second housing when the two housings are secured to the body.

With regards to claim 23, Harris discloses (figures 1-8) the cover claimed in claim 1, and further discloses the housing defining a second opening opposite

Art Unit: 3767

the single edge, the second opening being reclosable when the protective cover is secured to the body.

With regards to claim 24, Harris discloses (figures 1-8) the cover claimed in claim 23, and further discloses the second opening being defined along a second single edge, the second edge intersecting the axis, and the second edge being sealable to enclose the exposed portion within the housing.

With regards to claim 25, Harris discloses (figures 1-8) a method of providing a removable, resealable sterile protective cover for an exposed portion of a medical device extending along a longitudinal axis from a body, the cover comprising a housing, the housing defining an opening along a single edge, the method comprising: introducing the exposed portion across the single edge, into the housing; positioning the exposed portion of the medical device within the housing so that the edge intersects the axis; sealing the edge to enclose the exposed portion within the housing; and securing the housing relative to the body.

With regards to claim 26, Harris discloses (figures 1-8) a method of providing a removable, resealable sterile protective cover as claimed in claim 25, and further discloses it comprising the step of securing the housing to the body via an adhesive band about the opening.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

Art Unit: 3767

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 4, 6-7, 17 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Harris in view of Hermansson (US Patent publication No. 2004/0186450 A1) (Hereafter, Hermansson).

With regards to claim 4 and 17, Harris discloses (figures 1-8) the cover claimed in claim 3 and 16. However, Harris does not disclose the one or more flexible materials being water impermeable. Hermansson discloses (paragraph [0038]) the one or more flexible materials being water impermeable. Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the cover of Harris as disclosed by Hermansson to make the cover fluid tight.

With regards to claim 6 and 7, and 27 Harris discloses (figures 1-8) the cover and method claimed in claim 1 and 25. However, Harris does not disclose, the edge being biased for operation between a closed position and an open position. Hermansson discloses (paragraph [0046]), the edge being biased for operation between a closed position and an open position. Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the cover of Harris as disclosed by Hermansson for making the cover easy to operate.

Conclusion

References considered pertinent to Applicants' disclosure are listed on form PTO-892. All references listed on form PTO-892 are cited in their entirety.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael J. Anderson whose telephone number is (571) 272-2764. The examiner can normally be reached on M-F 7:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin C. Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Michael J Anderson
Examiner

Art Unit: 3767

Art Unit 3767

MJA

10/19/2007

KEVIN C. SIRMONS
SUPERVISORY PATENT EXAMINER

Kevin C. Sirmons